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Date: October 25, 2004

To: Examiner Tran

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From: Kristina Bieker-Brady, Ph.D., P.C.

J. Cooper McDonald, Ph.D.

Re: U.S. Application No. 09/559,984

In Situ Forming Hydrogels

Attorney Docket No. 50166/002001

Pages: 8

Message: Dear Examiner Tran:

Per your request, I have attached draft claim amendments that reflect the allowable subject matter agreed upon with Examiner Page. Claims 1, 2, 14, and 17 have been amended, and claims 9-11 have been cancelled. The claims are marked up assuming that the amendments filed on March 29, 2004 have been entered.

If you have any questions, please call me at the above number.

Very truly yours,

Patent Agent

Reg. No. 52,011

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U.S. Application No. 09/559,984 In Situ Forming Hydrogels Attorney Docket No. 50166/002001

- 1. (currently amended) A hydrogel precursor composition comprising:
- (a) a polymer comprising a water soluble polymer domain with at least two hydrophobic interacting groups attached thereto, wherein said hydrophobic interacting groups bind strongly to each other in an interchain manner to form a hydrogel under physiological conditions; and
- (b) a physical chemical protecting group that inhibits gel formation of said polymer by preventing said hydrophobic interacting groups from binding strongly in an interchain manner, wherein said physical chemical protecting group is a cyclodextrin.
- (currently amended) A hydrogel or hydrogel precursor composition comprising:
- (a) a polymer comprising a water soluble polymer domain with at least two hydrophobic interacting groups attached thereto, wherein said hydrophobic interacting groups bind strongly to each other in an interchain manner to form a hydrogel under physiological conditions;
- (b) a physical chemical protecting group that inhibits gel formation of said polymer by preventing said hydrophobic interacting groups from binding strongly in an interchain manner, wherein said physical chemical protecting group is a cyclodextrin; and

- (c) a molecule that disrupts an interaction between said physical chemical protecting group and said hydrophobic interacting groups.
- 3. (previously presented) The hydrogel precursor composition of claim 1, wherein said polymer domain comprises poly(ethylene glycol), poly(vinyl alcohol), poly(vinyl pyrrolidone), poly(ethyl oxazoline), poly(acrylic acid), poly(acrylamide), poly(styrene sulfonate), poly(amino acids), polysaccharides, or copolymers thereof.
- 4. (previously presented) The hydrogel precursor composition of claim 1, wherein said physical chemical protecting group is  $\beta$ -cyclodextrin.
- 5. (original) The hydrogel precursor composition of claim 1, wherein said hydrophobic interacting groups are positioned at the termini of said polymer domain.
- 6. (original) The hydrogel precursor composition of claim 1, wherein said hydrophobic interacting groups are positioned within said polymer domain.
- 7. (original) The hydrogel precursor composition of claim 1, wherein said hydrophobic interacting groups are hydrocarbous.
- 8. (original) The hydrogel precursor composition of claim 5, wherein said hydrocarbons are perfluorinated hydrocarbons.

- 9.-11. (cancelled)
- 12. (previously presented) The hydrogel precursor composition of claim 1, wherein said polymer domain comprises poly(ethylene glycol) and said hydrophobic interacting groups are perfluorinated hydrocarbons.
- 13. (original) The hydrogel or hydrogel precursor composition of claim 2, wherein said molecule that disrupts an interaction between said physical chemical protecting group and said hydrophobic interacting groups is a molecule that binds to said physical chemical protecting group better than said hydrophobic interacting groups binds to said physical chemical protecting group.
- 14. (currently amended) A method for forming a hydrogel in contact with a tissue, said method comprising the steps of:
- (a) providing a solution comprising a polymer comprising a water soluble polymer domain having at least two hydrophobic interacting groups attached thereto, wherein said hydrophobic interacting groups bind strongly to each other in an interchain manner to form a hydrogel under physiological conditions, and a physical chemical protecting group that inhibits gel formation of said polymer by preventing said hydrophobic interacting groups from binding strongly in an interchain manner, wherein said physical chemical protecting group is a cyclodextrin;

- (b) providing a molecule that disrupts an interaction between said physical chemical protecting group and said hydrophobic interacting groups;
- (c) combining said solution of step (a) with said molecule of step (b) to form a mixture, wherein prior to, during, or after said combining, said solution and said molecule are contacted with a tissue; and
- (d) allowing gel formation of the solution of the mixture of step (c) in contact with said tissue.
- 15. (previously presented) A method for forming a hydrogel in contact with a tissue, said method comprising the steps of:
- (a) providing a solution comprising a polymer comprising a water soluble polymer domain having at least two hydrophobic interacting groups attached thereto, wherein said hydrophobic interacting groups bind strongly to each other in an interchain manner to form a hydrogel under physiological conditions, and a water soluble organic solvent, said organic solvent preventing gel formation of said polymer; and
- (b) removing all or part of said organic solvent from said solution, wherein prior to, during, or after said removal, said solution is contacted with a tissue,

wherein said removing of said organic solvent in step (b) allows said hydrophobic interacting groups to bind strongly to each other in said interchain manner to form said hydrogel in contact with said tissue.

- 16. (previously presented) A method for forming a hydrogel in contact with a tissue, said method comprising the steps of:
- (a) providing a solution comprising a polymer comprising a water soluble polymer domain having at least two hydrophobic interacting groups attached thereto, wherein said hydrophobic interacting groups bind strongly to each other in an interchain manner to form a hydrogel under physiological conditions, and a water soluble organic solvent, said organic solvent preventing gel formation of said polymer; and
  - (b) contacting said solution with a tissue; and
- (c) allowing at least a portion of said organic solvent to be removed from said solution, wherein said removal of said organic solvent allows said hydrophobic interacting groups to bind strongly to each other in said interchain manner to form said hydrogel in contact with said tissue.
- 17. (currently amended) A method for incorporating a sensitive biological material into a hydrogel composition, said method comprising the steps of:
- (a) providing a solution comprising a polymer comprising a water soluble polymer domain having at least two hydrophobic interacting groups attached thereto, wherein said hydrophobic interacting groups bind strongly to each other in an interchain manner to form a hydrogel under physiological conditions, and a physical chemical protecting group that inhibits gel formation of said polymer by preventing said hydrophobic interacting groups from binding strongly in an interchain manner, wherein said physical chemical protecting group is a cyclodextrin;

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  - (b) providing a molecule that disrupts an interaction between said physical chemical protecting group and said hydrophobic interacting groups;
    - (c) providing a sensitive biological material;
  - (d) combining said solution with said molecule and said sensitive biological material to form a mixture; and
    - (e) allowing gel formation of the mixture of step (d).
  - 18. (previously presented) A method for incorporating a sensitive biological material into a hydrogel composition, said method comprising the steps of:
  - (a) providing a solution comprising a polymer comprising a water soluble polymer domain having at least two hydrophobic interacting groups attached thereto, wherein said hydrophobic interacting groups bind strongly to each other in an interchain manner to form a hydrogel under physiological conditions, and a water soluble organic solvent, said organic solvent preventing gel formation of said polymer;
    - (b) providing a sensitive biological material; and
  - (c) combining said sensitive biological material with said solution to form a mixture, wherein prior to, during, or after, said combining, all or part of said organic solvent is removed from said solution,

wherein said removal of said organic solvent allows said hydrophobic interacting groups to bind strongly to each other in said interchain manner to form said hydrogel.

- 19. (previously presented) The method of claim 16, wherein said organic solvent is removed by evaporation.
- 20. (previously presented) The method of claim 16, wherein said organic solvent is removed by diffusion into a bodily fluid.
- 21. (previously presented) The method of claim 16, wherein said organic solvent is removed by diffusion into an aqueous solution.